

United States
Department of .
Agriculture

March 14, 2005

Animal and Plant Health Inspection Service The Honorable Jon Dudas
Under Secretary for Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Mail Stop Patent Extension

Veterinary Services

PO Box 1450

Center for Veterinary Biologics

Alexandria, VA 22313-1450

510 S. 17th Street, Suite 104 Ames, IA 50010 (515) 232-5785 FAX (515) 232-7120 Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 5,275,813, filed by the Regents of the University of California, under 35 U.S.C. § 156. The veterinary biologic product claimed by the patent is Fel-O-Vax® FIV vaccine (Feline Immunodeficiency Virus Vaccine, Killed Virus), which was assigned VS Code No. 15A5.21 by the Center for Veterinary Biologics (CVB).

In the May 8, 2003, issue of the <u>Federal Register</u> (68 Fed. Reg. 24705-24706, Docket No. 03-045-1), the CVB published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notice provided that on or before November 4, 2003, 180 days after the publication of the determination, any interested person could file a petition with the CVB under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and the CVB has received no such petition. Therefore, the CVB considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely,

Richard E. Hill, Jr.

Director

Center for Veterinary Biologics

cc:

Kevin L. Bastian, Townsend & Townsend & Crew, San Francisco, CA

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